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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

MURGITROYD & COMPANY
Chartered Patent Agents
373 Scotland Street
Glasgow G5 8QA
ROYAUME-UNI

Date of mailing (day/month/year)
26 October 2001 (26.10.01)

Applicant's or agent's file reference
P26119A/GWO

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/01725

International filing date (day/month/year)
05 May 2000 (05.05.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
UNIVERSITY OF ULSTER
Faculty of Engineering
Newtonabbey
County Antrim BT37 0QB
United Kingdom

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [X] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
UUTECH LIMITED
University House
Cromore Road
Corelaine
Co Antrim
Northern Ireland, BT52 1SA
United Kingdom

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Idhir BRITEL
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 18 January 2001 (18.01.01)	
International application No. PCT/GB00/01725	**Applicant's or agent's file reference** P26119A/GWO
International filing date (day/month/year) 05 May 2000 (05.05.00)	**Priority date** (day/month/year) 06 May 1999 (06.05.99)
Applicant ANDERSON, John, McCune et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   15 December 2000 (15.12.00)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [ ] was

   [X] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
P26119A/GWO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 00/01725	05/05/2000	06/05/1999
Applicant		
UNIVERSITY OF ULSTER et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INT ATIONAL SEARCH REPORT

[redacted]national Application No
PCT/GB 00/01725

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/378

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
INSPEC, EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 796 221 A (HAGFORS N) 12 March 1974 (1974-03-12) column 2, line 52-65	1
A	US 4 549 547 A (REDKA WILLIAM ET AL) 29 October 1985 (1985-10-29) column 1, line 67 -column 2, line 37	1
A	US 5 735 887 A (ECHARRI ROBERT ET AL) 7 April 1998 (1998-04-07) column 9, line 9-17	1
A	US 5 411 537 A (MUNSHI MOHAMMED Z ET AL) 2 May 1995 (1995-05-02) abstract	1

☐ Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 September 2000	04/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Grossmann, C.

1

Form PCT/ISA/210 (second sheet) (July 1992)

INT ATIONAL SEARCH REPORT

Information on patent family members

[redacted]national Application No
PCT/GB 00/01725

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3796221 A	12-03-1974	NONE	
US 4549547 A	29-10-1985	NONE	
US 5735887 A	07-04-1998	NONE	
US 5411537 A	02-05-1995	NONE	

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) Internati nal Patent Classification 7 :
A61N 1/378

A1

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(21) International Application Number: PCT/GB00/01725

(22) International Filing Date: 5 May 2000 (05.05.00)

(30) Priority Data:
9910323.6 6 May 1999 (06.05.99) GB

(71) Applicant *(for all designated States except US)*: UNIVERSITY OF ULSTER [GB/GB]; Faculty of Engineering, Newtonabbey, County Antrim BT37 0QB (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ANDERSON, John, McCune [GB/GB]; 16 Torgrange, Holywood, County Down BT18 0NG (GB). EVANS, Noel [GB/GB]; 189 Gulladuff Road, Bellaghy, Magherafelt BT45 8LW (GB).

(74) Agent: MURGITROYD & COMPANY; Chartered Patent Agents, 373 Scotland Street, Glasgow G5 8QA (GB).

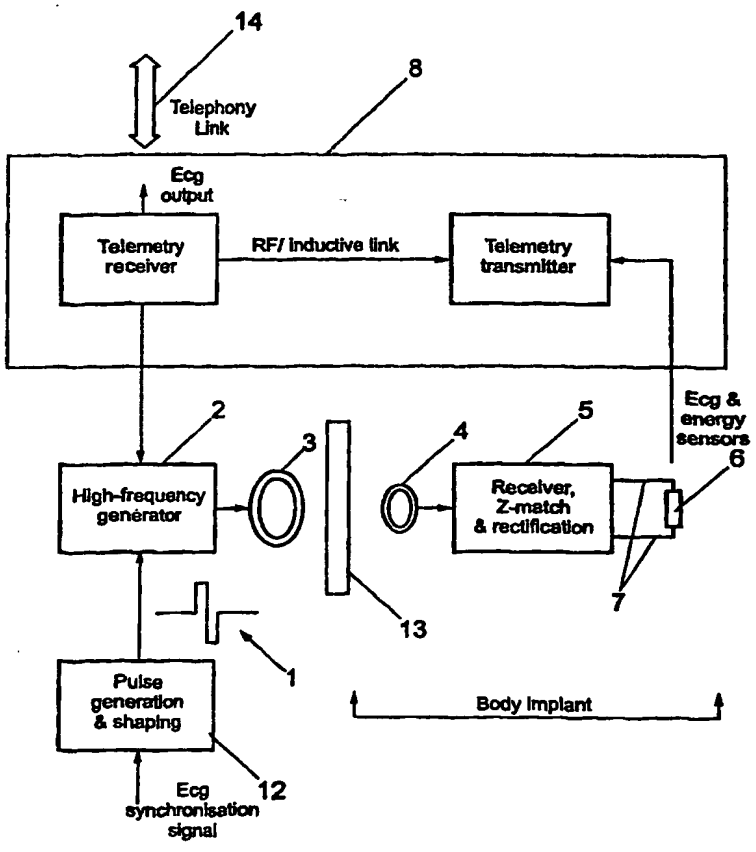
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CARDIAC DEFIBRILLATION

(57) Abstract

A defibrillator connected by catheters (7) to the heart (6) has an external circuit (2, 12) connected to a passive implanted circuit (5) by transdermal induction via voils (3, 4). For atrial defibrillation, pulses of 3–4J can be transmitted at about 7MHz without damage, using an implated coil (4) of 20mm diameter.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania
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3/prts

Cardiac Defibrillation

This invention relates to cardiac defibrillation, and in particular (but not exclusively) to an apparatus for delivering an electrical defibrillating signal to a human heart in the state of atrial fibrillation (AF), using transdermal energy transfer to a passive implanted device.

Atrial fibrillation is a common heart arrhythmia that increases in prevalence with age, with typically 10% of people over the age of 70 experiencing an incident. The process of cardioversion of AF to normal sinus rhythm (SR) has traditionally been attempted by pharmacological measures or transthoracic direct current shock. The former has been limited by variable cardioversion rates and the risk of side effects, in particular proarrhythmia. The latter requires sedation or anaesthesia and high energy shocks, and there is a high recurrence rate. For these reasons, there has been interest in catheter-based transvenous atrial defibrillation and its potential use in an implantable atrial defibrillator. However, atrial implantable defibrillators are complex devices requiring on-board pattern recognition with complex recording and follow-

up procedures. The need for electrical charging circuitry using active devices adds to the complexity and weight of the implant.

The present invention provides an apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes implantable in the heart.

In a preferred form of the invention, for use in atrial defibrillation, the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, typically about 7MHz.

Most preferably, the implantable circuit contains only passive components.

From another aspect the invention provides a method of cardiac (preferably atrial) defibrillation which comprises transmitting pulses of controlled shape and energy transdermally by high frequency magnetic induction to a substantially passive implanted circuit which includes electrodes implanted in the heart.

It is known to transfer energy transdermally by induction, but only for purposes of recharging batteries in implanted devices such as pacemakers or continuously powering implanted devices such as pumps. It has not hitherto been proposed to use such

techniques to transfer controlled waveforms for high-energy physiological stimulation.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows the elements required for controlled, transdermal energy delivery to a cardiac load;
Figure 2 illustrates the circuitry required external to the body;
Figure 3 represents the body-internal circuitry; and
Figure 4 illustrates waveforms in the apparatus.

In the apparatus (Figure 1), an appropriately synchronised trigger pulse is firstly generated, based on the subject's electrocardiogram (ecg). This pulse, after shaping in a pulse generation and shaping circuit 12 to a waveform 1 suitable for AF conversion, is used to amplitude modulate a radio frequency (RF) carrier generator 2 at a power level consistent with the transmission of 1-5 J of energy to the internal load, itself nominally 50 Ω resistive. The transmission path takes the form of a pair of coaxially-aligned transmit 3 and receive 4 inductors constructed in the form of an RF transformer. The diameters of the coils 3 and 4 are set so as to optimise energy transfer at a physical spacing not less than the thickness of the thoracic wall 13. Both inductors are wound with enamelled copper wire. The transmitting coil 3 is mounted on an insulated paddle to facilitate adjustment in its placement on the subject's body. The implanted circuitry is mounted on a printed circuit board and consists of the receiving coil 4 connected to impedance matching, rectification and wave-shaping components 5. The final defibrillating signal is connected to the

heart (indicated as an electrical load 6) by catheters 7, one placed in the lateral right atrium (RA) and the other in the distal great cardiac vein via the coronary sinus. Alternatively, any conventional atrial defibrillation delivery system may be used.

In one example, the coils 3 and 4 are designed to give optimum inductive coupling at a centre-to-centre spacing of 20mm. Given a maximum diameter, for practicability, of the receiving coil 4 of 35mm, the transmitting coil 3 has a diameter of 53mm. Both inductors are wound with 1.5mm enamelled copper wire. The transmitting coil 3 is arranged as a solenoidal coil, spaced at one turn. The receiving coil 4 is pile-wound to conserve space in the final implant.

Both inductors in the apparatus are tuned to resonance at the selected operating frequency of the system, typically in the range 3-30 MHz. As seen in Fig. 2, the transmitter uses series tuning by capacitor 9. Fig. 2 also shows a 50 ohm feed 15 from the generator 2, giving an operational loaded Q of approximately 5. Referring to Fig. 3, the receiving coil is parallel tuned, with capacitive matching to the load 6 by means of capacitors C1 and C2. A radio-frequency choke 11 provides a DC path for rectifier current. Rectification and shaping is effected in circuit 16.

Optionally, as shown in Figure 1 a telemetry link 8 may be incorporated to provide ecg monitoring and feedback-derived, automatic tuning of the energy delivery system. Such a link may also be powered from energy delivered transdermally, by using a low-power transfer to power up the telemetry link, or to charge an on-board battery. Alternatively, the ecg could be transmitted via the induction coils using a suspended

carrier technique.

As is also indicated in Figure 1, the external circuitry may include a remote communication link 14, which may be via telephone communication (landline or GSM) or via a radio link. This would, for example, enable the patient's ecg to be transmitted to a hospital for monitoring and for inspection by a physician. Defibrillation could be activated remotely, and spoken instructions could be conveyed to the patient.

Atrial defibrillation currently requires a pulse energy of about 3 to 4J. By using a tuned inductive coupling as described, typically at a frequency about 7 MHz, these energy levels can be transmitted transdermally while maintaining control of pulse shape and timing. It is contemplated that by refining the pulse shape, duration and timing required to achieve defibrillation the energy necessary could be reduced to 1J or less, which would be painless to the patient and remove any need for sedation.

The pulse form 1 shown in Figure 1 is a biphasic pulse, which is the form we currently prefer. However, other pulse forms and hence RF envelope shapes may also be used, such as monophasic and multiple. Fig. 4 illustrates waveforms of the apparatus in more detail. Fig. 4a is a typical trigger input from an ecg. Fig. 4b shows a typical RF output envelope to the coil 3 as a single pulse. Fig. 4c shows an alternative RF output envelope as a burst of two or more pulses. All pulses can be controlled in width, and the inter-pulse gap of Fig. 4c is programmable. Each RF pulse, after transmission and rectification, results in either a monophasic or a biphasic (baseband) voltage waveform

suitable for driving the cardiac load. Fig. 4d shows a monophasic pulse 17 and a biphasic pulse 18 which can be produced from the single pulse of Fig. 4a.

Although described above with particular reference to atrial defibrillation, the invention could find use in ventricular defibrillation. Here, though, the required energy levels are much higher (typically about 15J).

It will be appreciated that one of the benefits of the embodiment described is that the implanted hardware is entirely passive and does not require any implanted power source. However, the invention does not exclude the possibility of some active components being implanted, with a reduced requirement for an internal source of power.

CLAIMS

1. An apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes implantable in the heart.

2. An apparatus according to claim 1, for use in atrial defibrillation, in which the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, preferably about 7MHz.

3. An apparatus according to claim 1 or claim 2, in which the signal generating means comprises a radio frequency generator switched or gated under the control of a pulse generation and shaping means which in turn is responsive to an ecg synchronisation signal.

4. An apparatus according to claim 3, in which the ecg synchronisation signal is provided via a telemetry transmitter implanted in the patient.

5. An apparatus according to any preceding claim, in which the external circuit further includes a telephony link by which the ecg may be transmitted to, and/or the apparatus controlled from, a remote location.

6. An apparatus according to any preceding claim, in which the external and implantable circuits include

impedance matching components to achieve a high degree of tuning.

7. An apparatus according to claim 6, in which the inductive coupling is tuned to resonance.

8. An apparatus according to claim 8, in which the inductive coupling is tuned to resonance by use of series resonance in the external circuit and parallel resonance in the implantable circuit.

9. An apparatus according to any preceding claim, in which the implantable circuit contains only passive components.

10. A method of cardiac defibrillation which comprises transmitting pulses of controlled shape and energy transdermally by high frequency magnetic induction to a substantially passive implanted circuit which includes electrodes implanted in the heart.

11. The method of claim 10, in which the electrodes are implanted to provide atrial defibrillation.

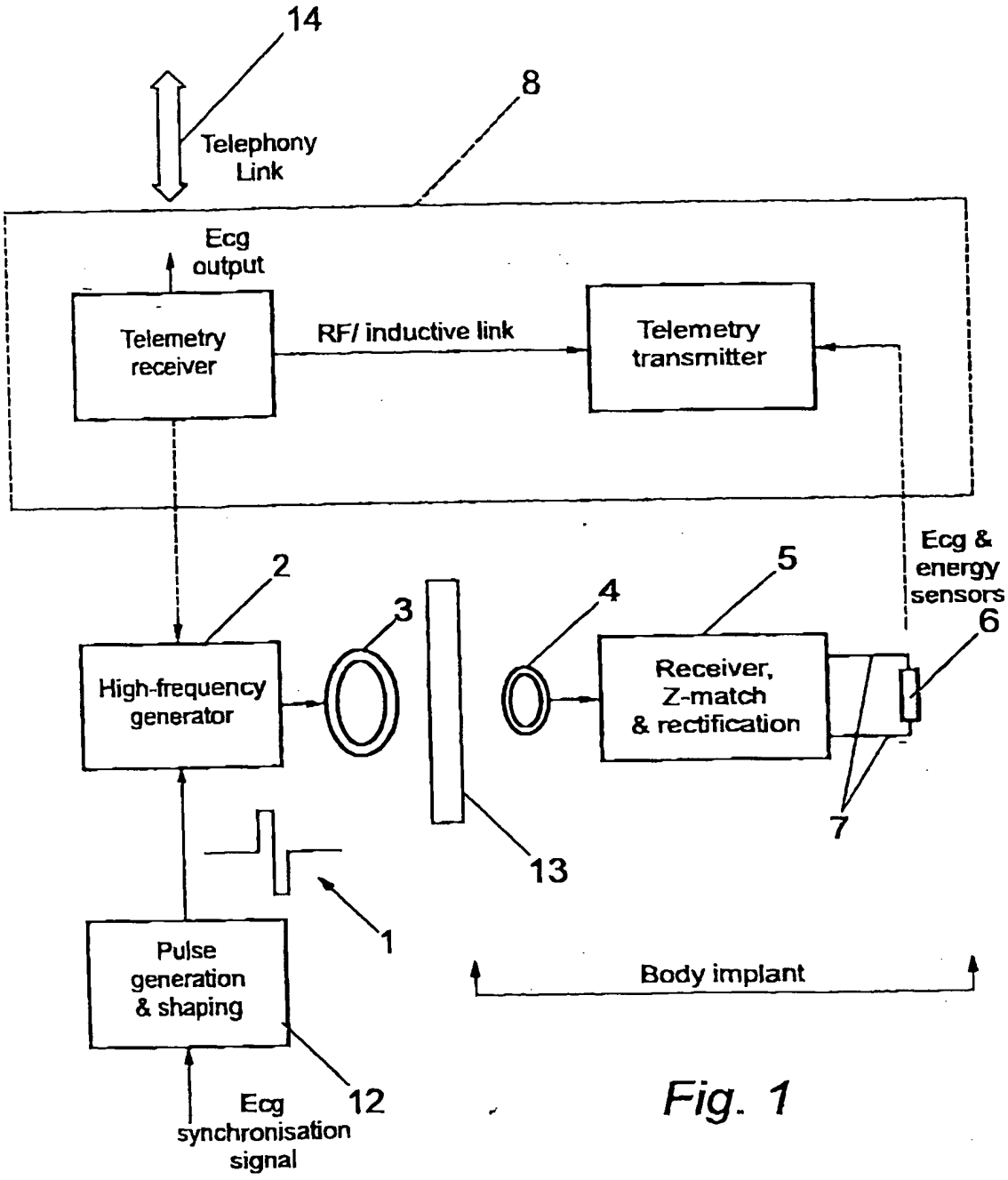
14
Telephony Link
8
Ecg output
Telemetry receiver
RF/ inductive link
Telemetry transmitter
Ecg & energy sensors
2
3
4
5
6
High-frequency generator
Receiver, Z-match & rectification
7
13
1
Pulse generation & shaping
Body implant
12
Ecg synchronisation signal

Fig. 1

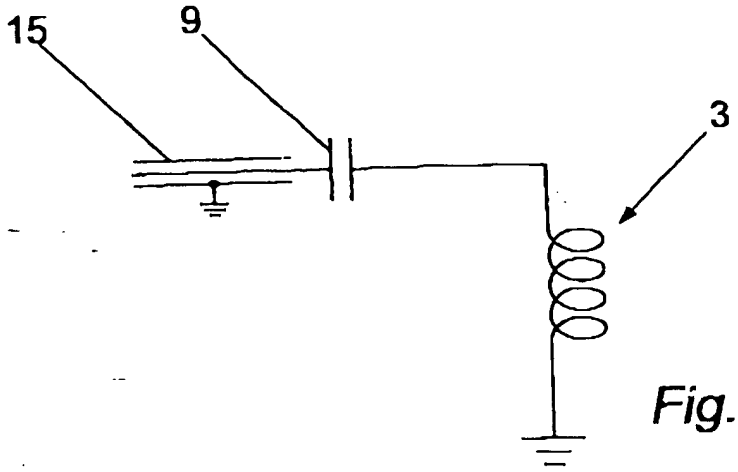

Fig. 2

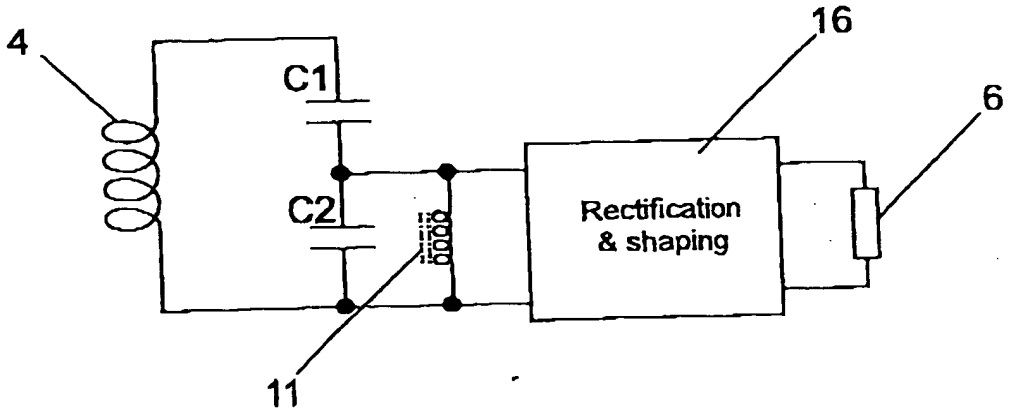

Fig. 3

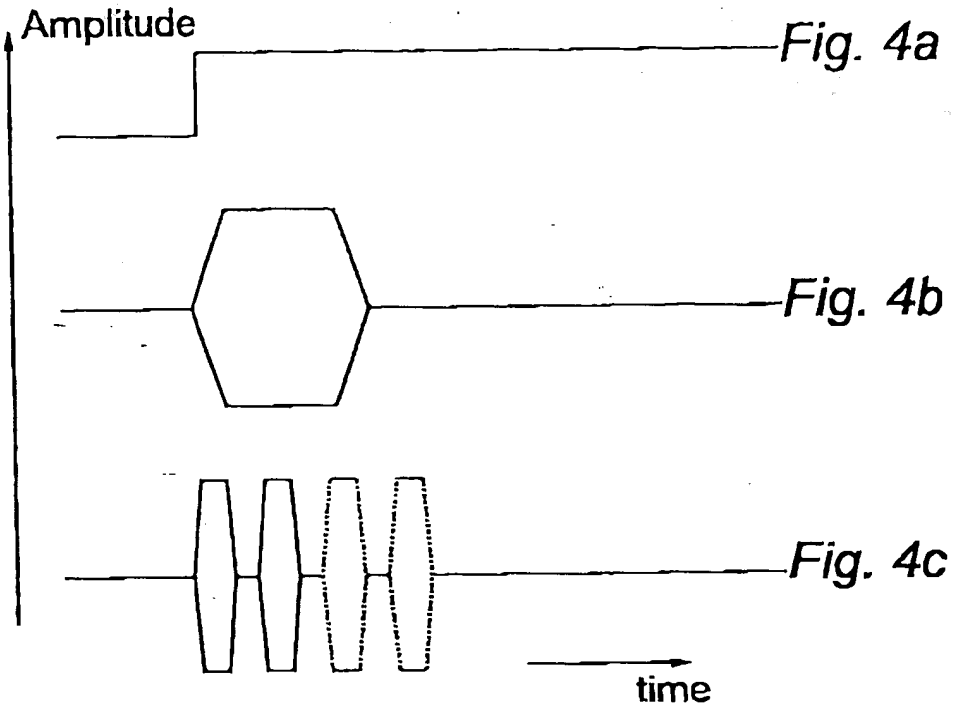

Fig. 4a

Fig. 4b

Fig. 4c

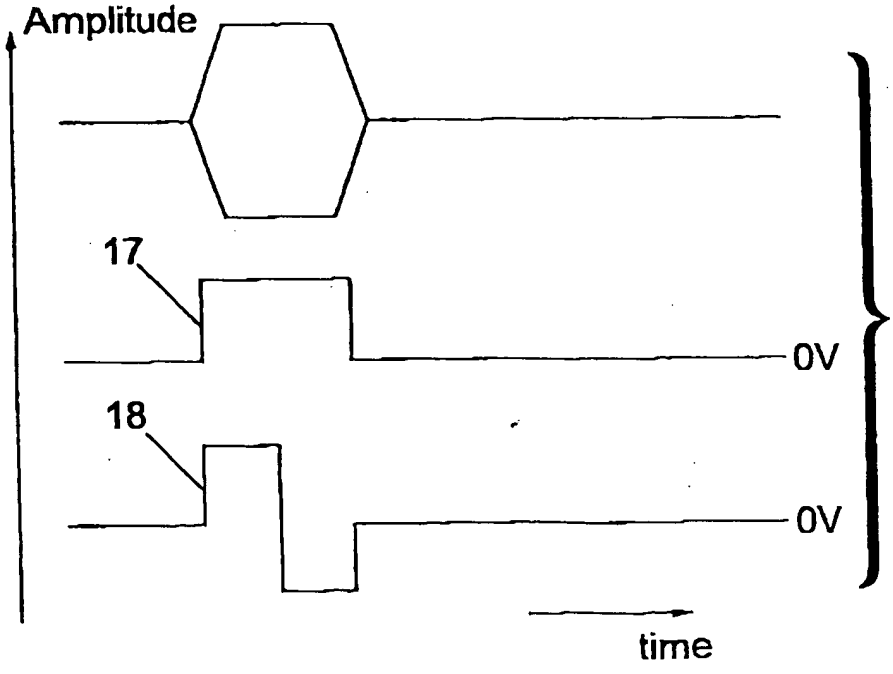

Fig. 4d

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MURGITROYD & COMPANY
Chartered Patent Agents
373 Scotland Street
Glasgow G5 8QA
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	17.05.2001
Applicant's or agent's file reference P26119A/LMM/MEA	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/01725	05/05/2000	06/05/1999

Applicant
UNIVERSITY OF ULSTER et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Ullrich, C Tel.+49 89 2399-2322

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P26119A/LMM/MEA		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/01725	05/05/2000	06/05/1999
International Patent Classification (IPC) or national classification and IPC		
A61N1/378		
Applicant		
UNIVERSITY OF ULSTER et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report
   II ☐ Priority
   III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   VI ☐ Certain documents cited
   VII ☒ Certain defects in the international application
   VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15/11/2000	17.05.2001
Name and mailing address of the international preliminary examining authority:	Authorized officer
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Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01725

I. Basis of the report

1. With regard to the elements of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, pages:

1-6 as originally filed

Claims, No.:

1-11 with telefax of 26/04/2001

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments hav resulted in th cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01725

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 10,11.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 10,11.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 2-9

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01725

	No:	Claims	1
Inventive step (IS)	Yes:	Claims	2-4,9
	No:	Claims	5-8
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/GB00/01725

ad I:

1. Claim 1 has been amended by adding the passage "and in which the rectification circuit drives the electrodes directly with pulses of a shape which is determined by the signal generating means of the external circuit". The meaning of this passage is unclear (Art.6 PCT) and does not appear to supported by the original disclosure contrary to the requirements of Art.19(1),(2) PCT.

   Concerning the clarity, this passage appears to be contradictory in itself. Assuming that the external source transmits bipolar pulses as indicated in fig.4b and as explained in the description page 5, last paragraph, these bipolar pulses are received by the implantable coil and the signal is then rectified. Thereby its shape is necessarily altered to a monopolar signal. How can one then say that the shape of the pulses delivered to the heart is determined by the signal generating means of the external circuit. Apparently, the shape of the delivered pulses is determined by the rectification circuit of the implantable circuit.

ad V:

1. In this report reference is made to the following document:

   D1... US-A-5 411 537
   D2... US-A-3 796 221
   D3... US-A-4 549 547

2. Document D2 discloses an implantable apparatus for delivering electrical stimulation energy to a body organ. It is generally known that defibrillation may also be achieved by using low energy stimulation pulses. In that sense, the D2 apparatus is also considered suitable for cardiac defibrillation. The D2 apparatus comprises all constructive features as defined in claim 1:

   - an external circuit (48) and an implantable circuit (12, cf. fig.1),
   - the external circuit including an induction transmitting coil (32) and signal generating means (fig.3) for applying RF pulses of predetermined shape to the transmitting coil (cf. col.1, lines 40-46);
   - the implantable circuit including an induction receiving coil (68) for receiving

pulses when the two coils are in proximity, and a rectification circuit ((70,72), col.5, lines 16-19) having an input connected to the receiving coil (cf. fig.4) and an output driving electrodes implantable in the heart (cf. figs.4-9).

Accordingly, the apparatus claim 1 in its purely constructive features lacks novelty in view of D2 so that the requirement of Art.33(2) PCT is not met.

3. The additional features as defined in current dependent claims 5-8 appear conventional in the context of implantable stimulators. Their inclusion in a device as known from D2 does not provide for inventive subject-matter in that it merely amounts to the use of a known feature for its known purpose (Art.33(3) PCT):

claim 5:

A telephone link for transmission of data, eg. ECG data is generally known in the art. the D1 apparatus has a telemetry unit (26) by means of which ECG data may be read into the microprocessor;

claim 6: Impedance matching components, see D1, col.10, line 25: ferrite core;

claims 7,8:

That the inductive coupling is tuned to resonance is obvious when optimisation of energy transfer is required as is the case with the D1 apparatus; that such resonance tuning may be achieved by use series and parallel resonance circuits is generally known to one skilled in the art.

4. The features as defined in claims 2-4 and 9 do not appear to be known in the present context. The use of RF in the range of 3-30MHz does not appear obvious in the context in that D1 suggests 10 to 40 kHz (col.10, lines 25,26) and D3 suggests use of 60 kHz (col.3, line 5). This feature is considered advantageous for a defibrillator when higher pulse energies need to be transmitted transdermally. Claim 2 and claims 3-9 when dependent on the former thus meet the requirements of Art.33 PCT.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/GB00/01725

ad VII:

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (see document D2 and item V.2. above) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, documents D1 and D2 are not identified in the description and their relevant prior art has not been mentioned, although the latter does not apply for D1 in view of page 2, last paragraph of the description of this application.

ad VIII:

1. The description should have been brought into conformity with claim 1. A variance to the invention as defined in the claim 1 appears to exist at page 4, lines 34,35.

Claims

1. An apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving said pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes which are implantable in the heart; and in which the rectification circuit drives the electrodes directly with pulses of a shape which is determined by the signal generating means of the external circuit.

2. An apparatus according to Claim 1, for use in atrial defibrillation, in which the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, preferably about 7MHz.

3. An apparatus according to Claim 1 or Claim 2, in which the signal generating means comprises a radio frequency generator switched or gated under the control of a pulse generation showing means which in turn is responsive to an ecg synchronisation signal.